



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 15 and 16, 2016, from 8 a.m. to 6 p.m.

Location: Holiday Inn Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel telephone number is 301-948-8900.

Contact Person: Dimitrus Culbreath, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3610, Silver Spring, MD 20993-0002, 301-796-6872, Dimitrus.Culbreath@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory

committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the Agency's Web site at

<http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On March 15, 2016, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System sponsored by Abbott Vascular. The Absorb GT1 BVS System is a temporary scaffold that will fully resorb over time and is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to de novo native coronary artery lesions (length \leq 24 millimeters (mm)) with a reference vessel diameter of \geq 2.5 mm and \leq 3.75 mm.

On March 16, 2016, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the AngelMed Guardian System sponsored by Angel Medical Systems, Inc. The AngelMed Guardian System is an implantable cardiac monitor intended to alert patients to ST segment shifts indicating coronary ischemia. The AngelMed Guardian System is intended for use in patients with prior acute coronary syndrome events, and at risk for recurrent events, to ST segment changes indicating cardiac ischemia.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at

<http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 1, 2016. Oral presentations from the public will be scheduled on March 15 and 16, 2016, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 22, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 24, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at artair.mallett@fda.hhs.gov, 301-796-9638, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 11, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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